

# Overview of DQRS, FARS and BPDRs

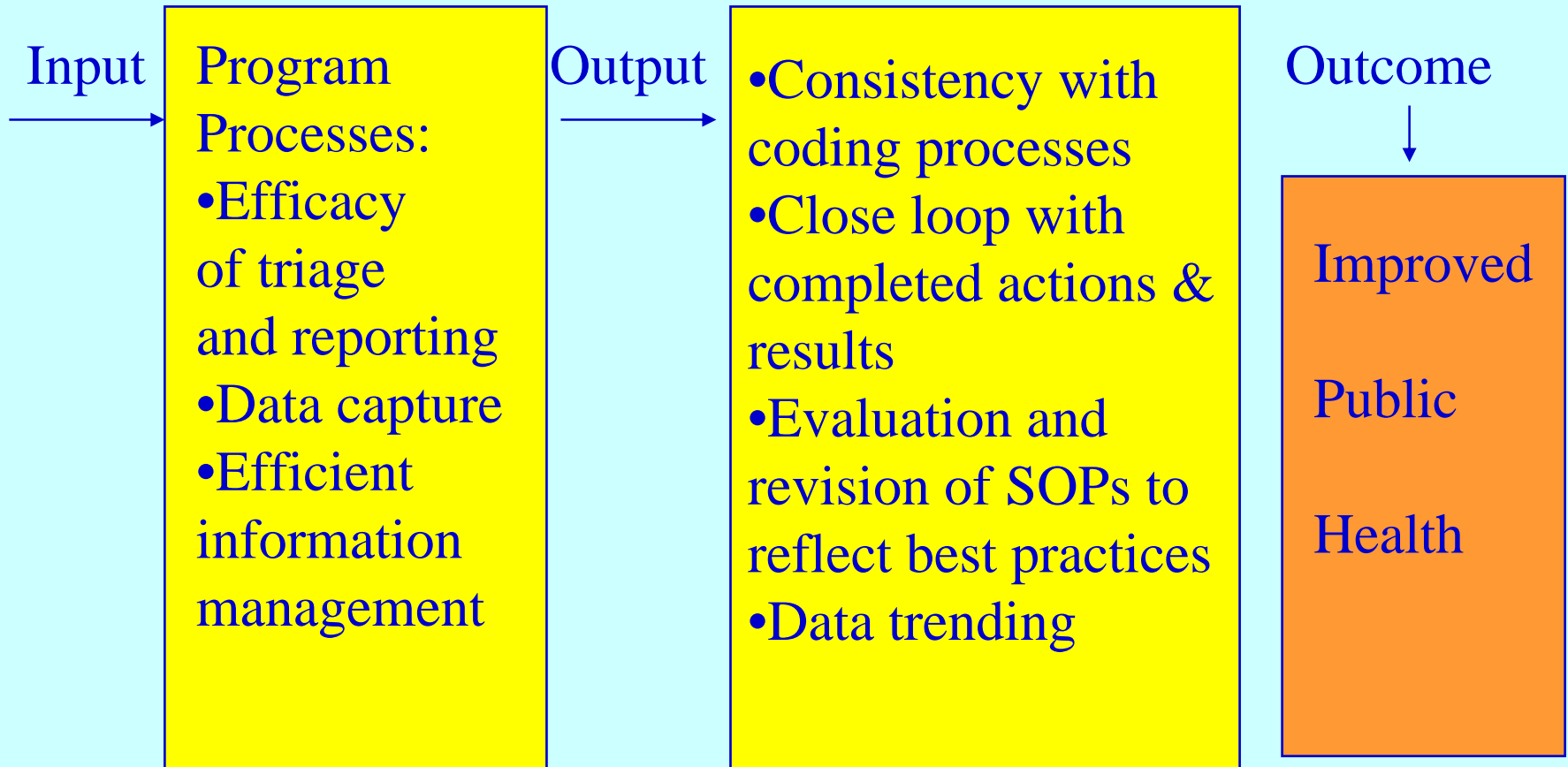


*CAPT Juliaette Johnson, R.N., M.S.*  
*Division of Compliance Risk Management & Surveillance*

# Mission

- Assuring that safe and effective drugs are available to the public
- Reduce public health risks associated with the quality, safety, and effectiveness of the nation's marketed drugs
- High-quality pharmacovigilance and risk minimization practices
- Utilize strategic problem solving to identify, evaluate, and prioritize risks related to drug quality, safety, effectiveness, and availability.

# Performance Goals/Objectives



# NDA Field Alert Reports (FARs)

- CFR 314.81 (b)(i) and (ii)
- NDAs and ANDAs
- Effective May 23, 1985

## 21 CFR 314.81 (1)(i) Required Reporting

Any incident that causes the drug product  
or its labeling to be mistaken for, or  
applied to, another article  
(adulterated or misbranded)

## 21 CFR 314.81 (1)(ii) Required Reporting

- Bacterial contamination
- Significant chemical, physical or other change
- Product deterioration
- Out-of-specification

## Reporting Requirements

- Applicant holders are required to submit NDA/ANDA Field Alert reports on drug products manufactured or distributed within or outside the U.S.
- U.S. Office/Agent (21 CFR 314.50(a)(5))-responsible for reporting to FDA district office where registered/located
- Notify the district office within 3 working days

# Reporting Requirements

- Information may be provided by telephone or other rapid communication means, with prompt written follow-up
- Form FDA 3331
  - or equivalent/variation
- Internet Availability of Form 3331 - Word Format

<http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>

or

<http://forms.psc.gov/forms/MSWFDA/FDA-3331.doc>

# Changes to Field Alert Form (#3331)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>NDA-FIELD ALERT REPORT</b>		TO: (NAME AND ADDRESS OF DISTRICT)	
TYPE OF REPORT <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up <input type="checkbox"/> Final			
In accordance with Section 18.81(b)(1)(i) and (ii) of the New Drug and Antibiotic Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:			
NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.		NDC No.	
GENERIC NAME OF DRUG PRODUCT		TRADE NAME (if any) OF DRUG PRODUCT	
FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED		FEI	
DOSAGE FORM, STRENGTH, AND PACKAGE SIZE(S)			

# 3 Working Days Required to Report

- Starts
  - Firm becomes aware of a reportable problem
    - Complaint
    - Internal testing
    - Unconfirmed problem
    - Confirmed problem

# Firm Reporting

- FAR Required
  - Further investigation required
  - Corrective action initiated
    - e.g., Formulation revision, labeling change
  - Product Recall
- FAR Not Required
  - Problem is resolved within 3 working days
    - e.g., Analytical lab error

# District Responsibilities

- Submit a copy of each FAR
  - **Initial**
    - within 5 working days
  - **Follow-up**
  - **Final**
    - Upon receipt and district evaluation

## District Responsibilities (cont'd)

- Submit district action plan
  - Available investigational information
- Assess significance of FAR
  - Conduct appropriate follow-up
- Determine compliance with regulation
  - Routine inspections
  - Pre-approval inspections

# District Surveillance Program Team Contact

- Designated by District
  - >Normally DQRS coordinator for the District

# Surveillance Program Team Responsibilities

- Liaison between District Offices and CDER
- Receive all FARS
- Forwards FARs to appropriate CDER  
Offices/Divisions
  - Subsequent review & actions are responsibility  
of the receiving Offices/Divisions

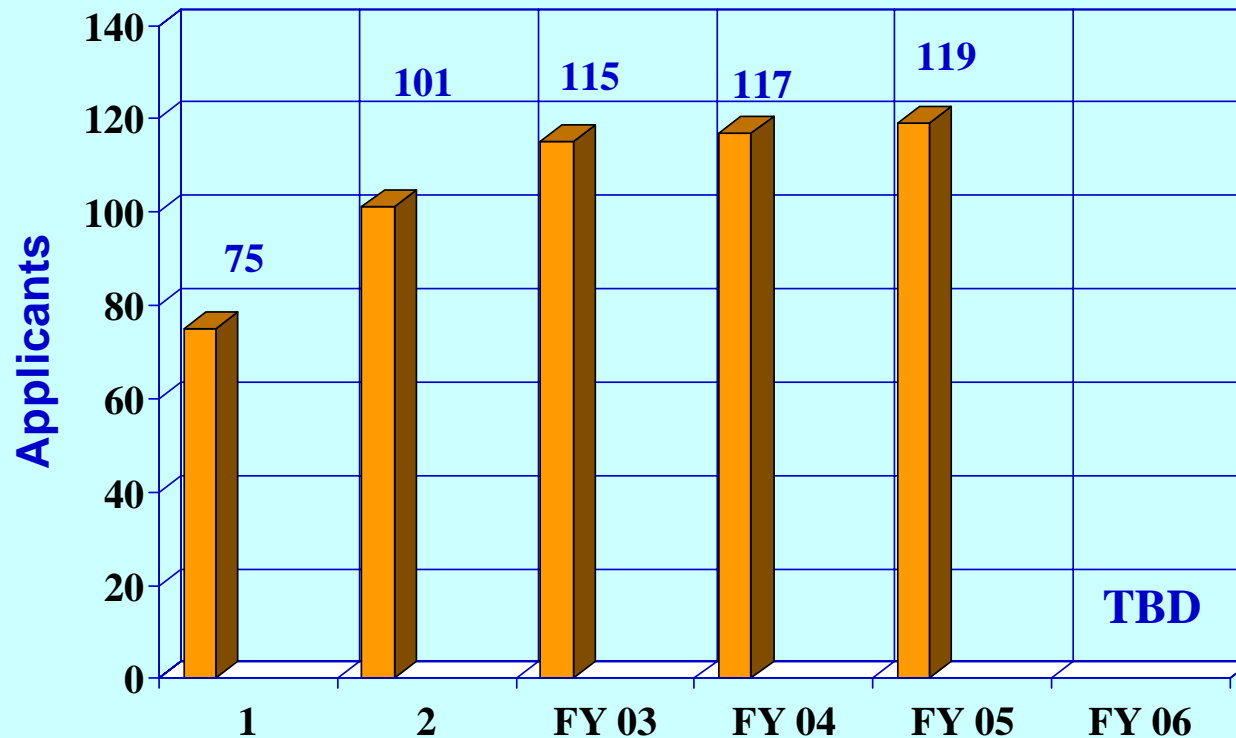
# CDER Review Divisions Responsibilities

- Review FAR
  - Determine completeness for review
  - Assure any corrective action(s) is not in conflict with NDA/ANDA requirements
- Assures that a supplement has been submitted and approved for the NDA/ANDA
- FAR becomes part of the approved NDA/ANDA

## HFD-330 Regulatory Actions

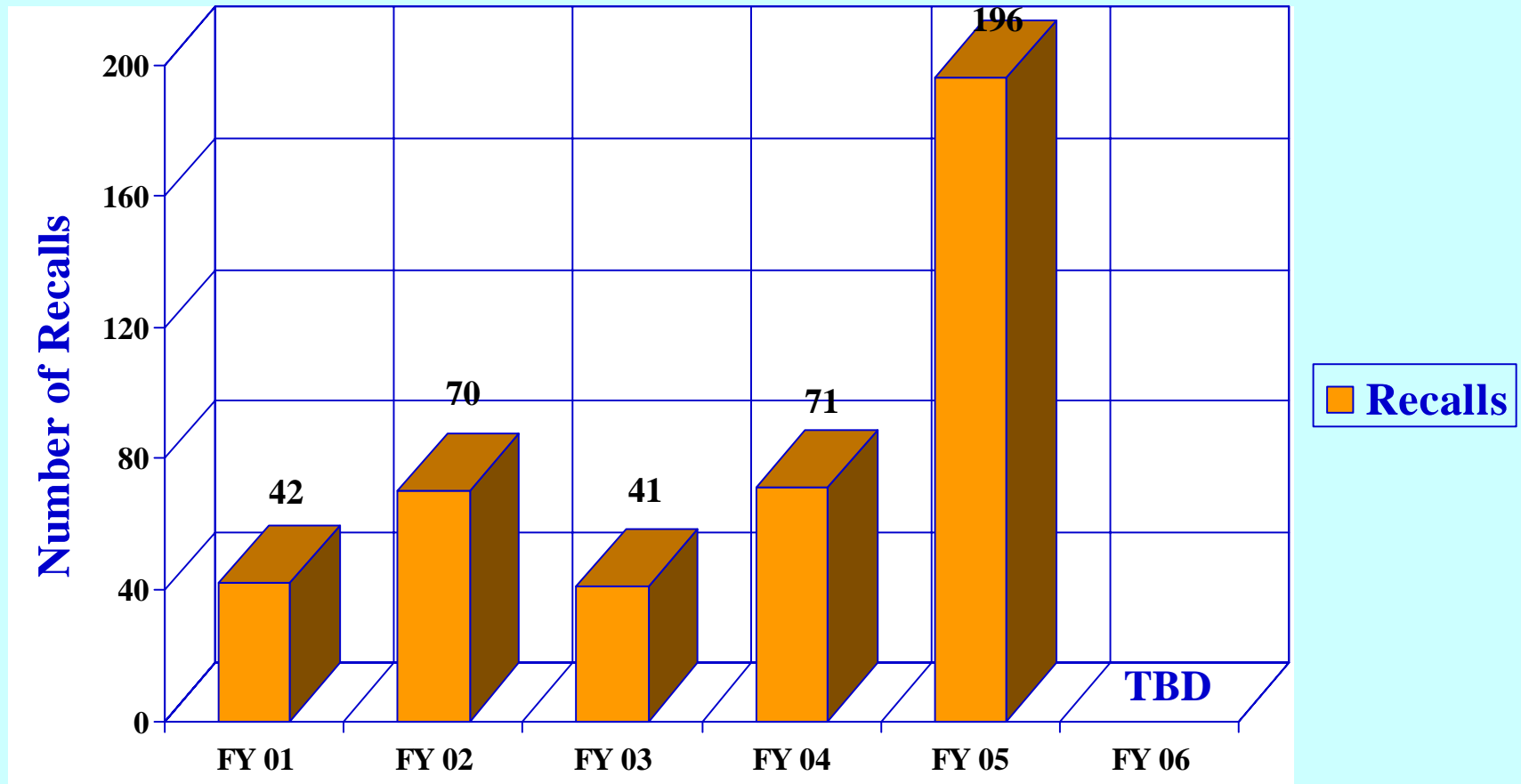
- HFD-330 approves regulatory actions regarding FAR reporting
- Warning Letter
  - When appropriate
    - Significance of violation(s)
    - Previously cited violation(s)
    - Concurrence with headquarters

# Number of Applicants Submitting FAR Reports FY 01 - FY 05

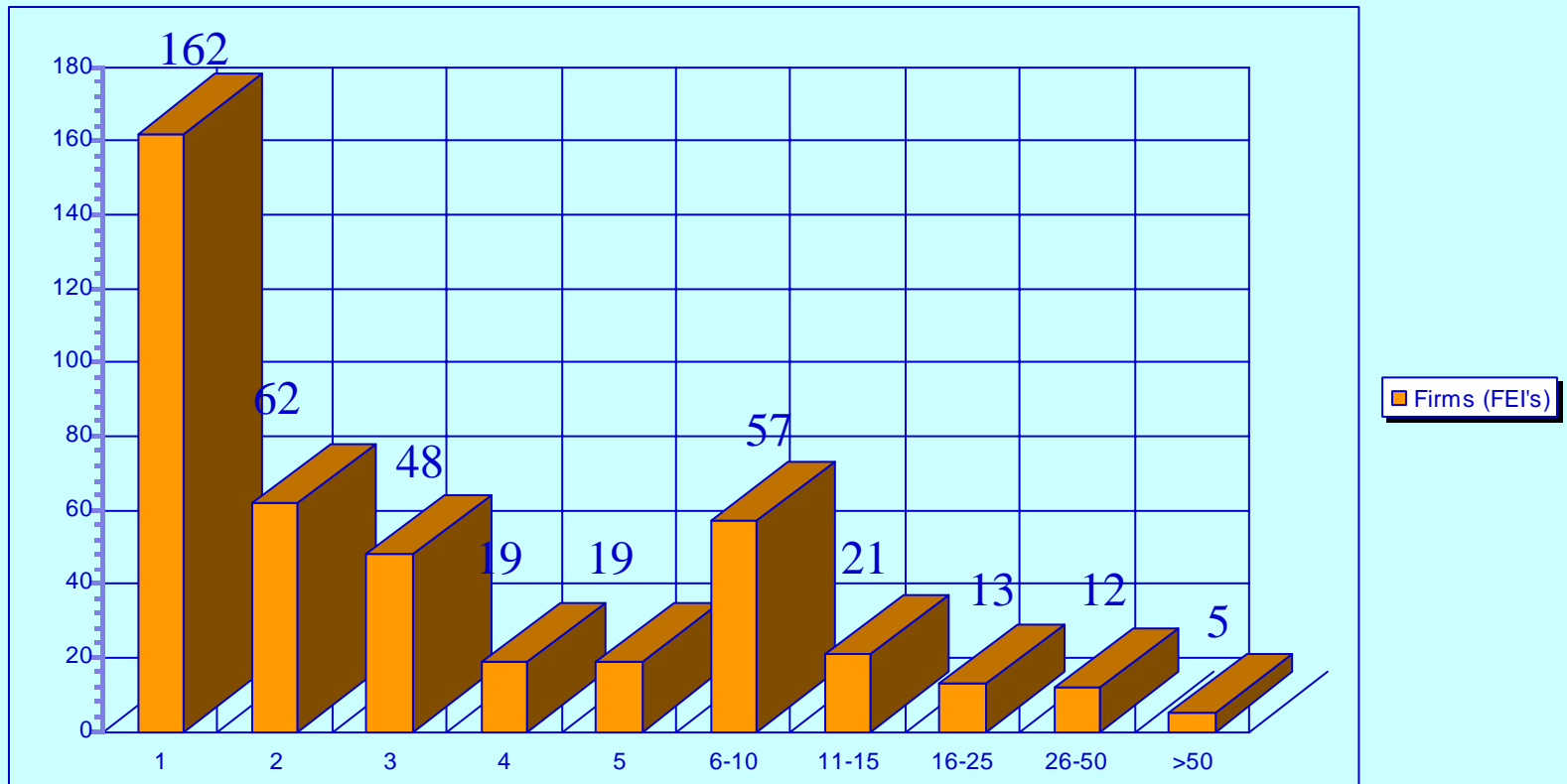


# Recalls Resulting from Field Alerts

## FY 01 - FY 05

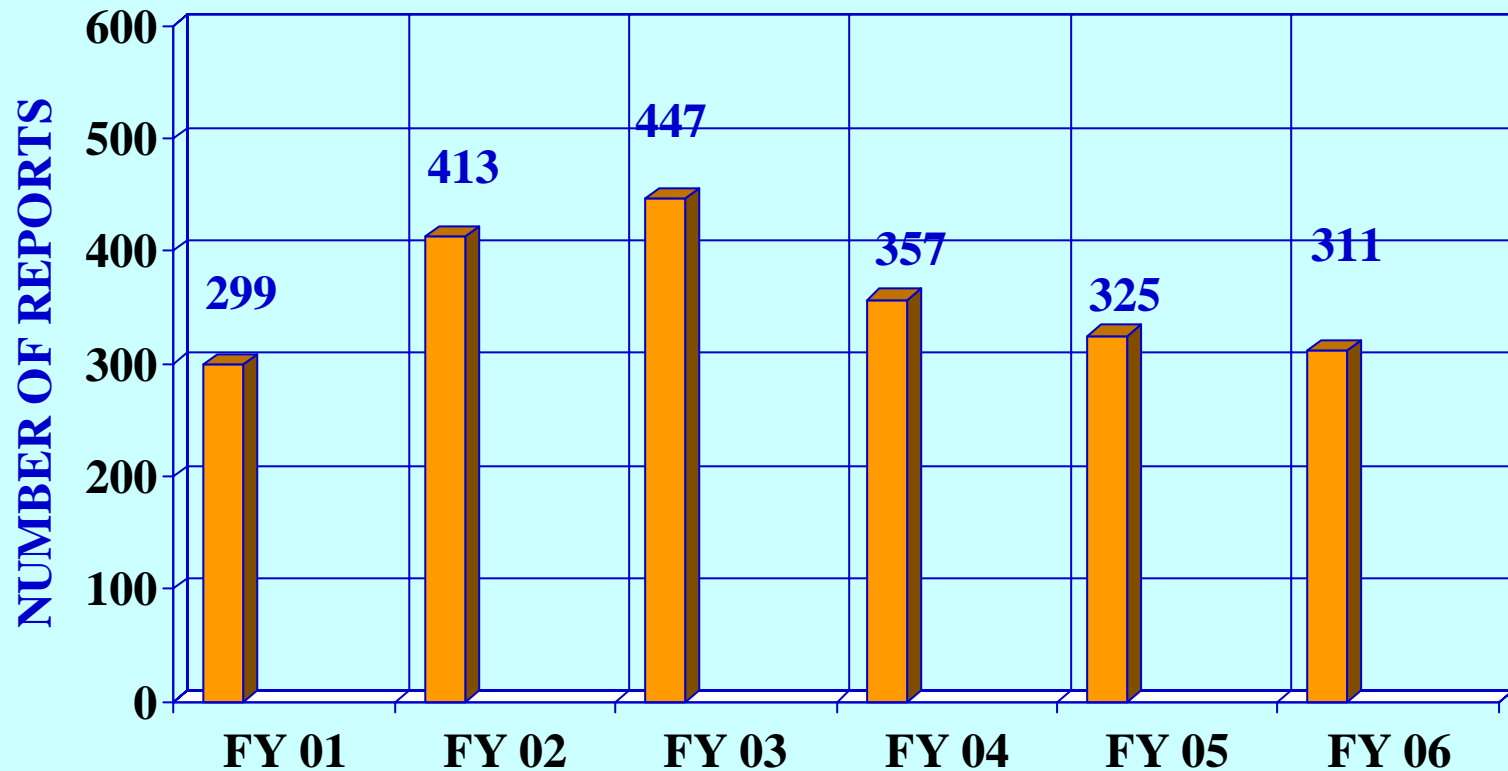


# FARS Reports for 2000 -2006



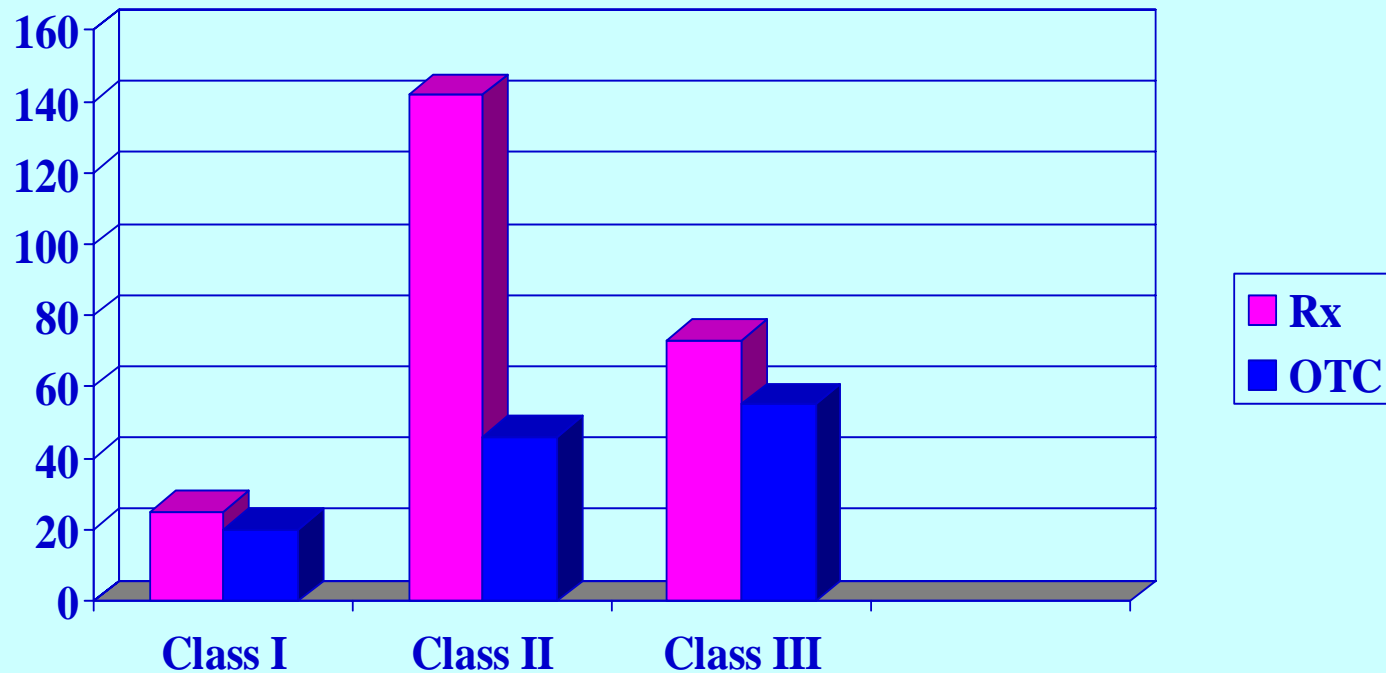
Number of FARS

# Total Field Alerts Received FY 01 - FY 06



# Summary of FY 06 Recalls

**Total Recalls - 361 for FY 06**

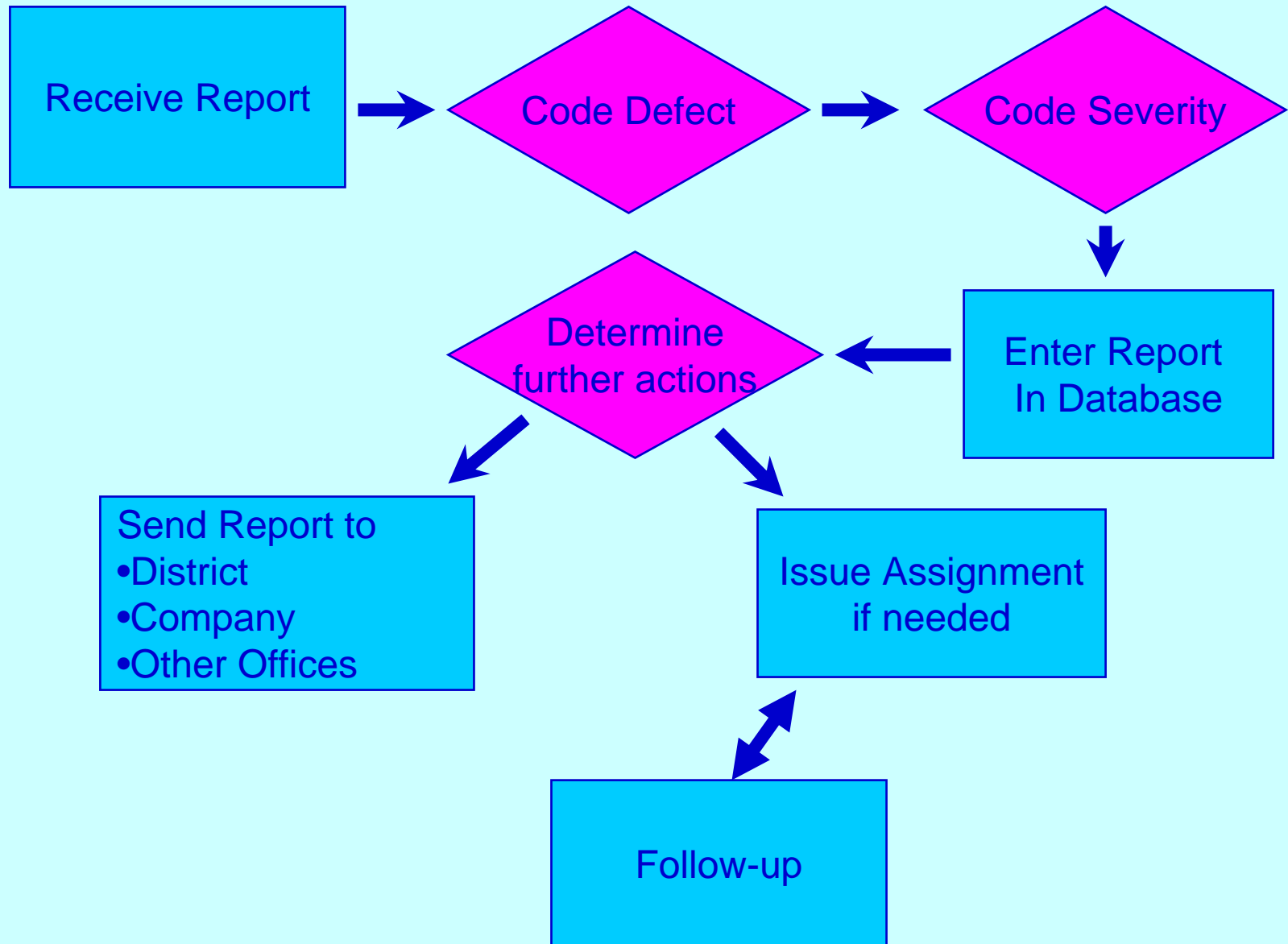


# Drug Quality Reporting System (DQRS)

# DQRS Background

- 1971 - 1988      Drug Product Problem Reporting Program (DPPR)
- 1988 - 2000      USP Drug Product Problem Reporting Program  
(USP Program terminated August 31, 2000)
- 1988 - 1993      Drug Quality Reporting System (DQRS)
- 1993 - Present    MedWatch Program

# Proposed DQRS Workflow Model



# DQRS Program Objectives

- Rapidly identify significant health hazards
- Detect industry problems and trends
- Operate a centralized reporting system

# Surveillance Program Team Responsibilities

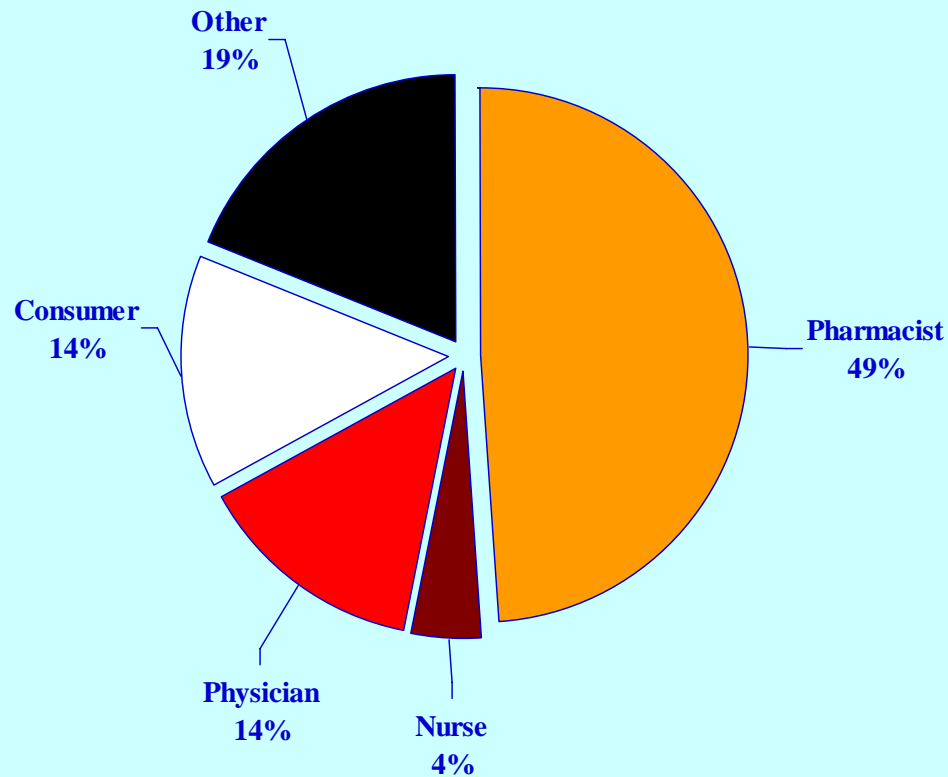
- Screen all reports
  - Review/Evaluate
  - Prioritize
  - Potential Health Hazard
- Collect and Verify Information
  - Contact reporter
  - Contact CDER review division



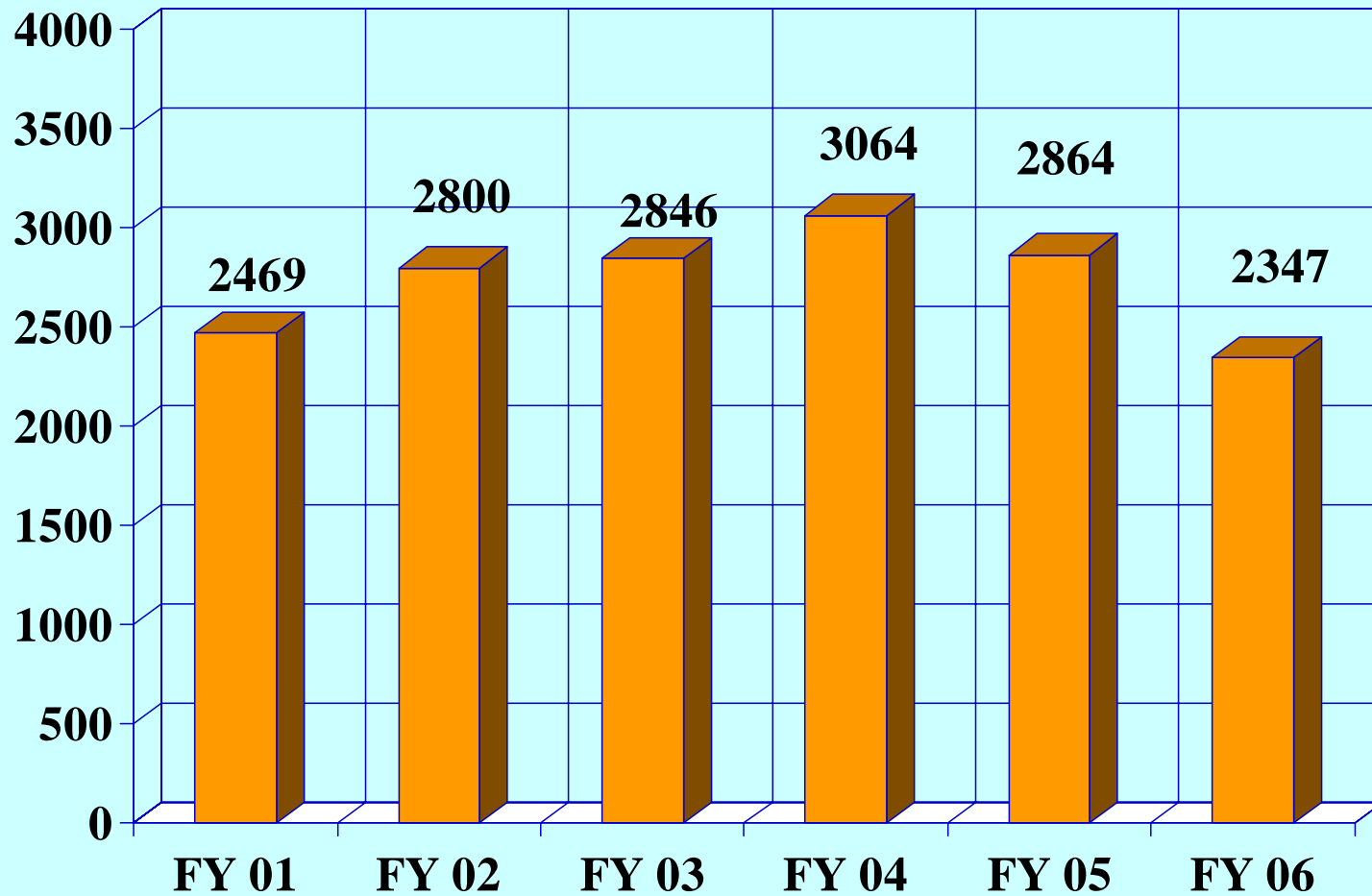
# Classification of Reports

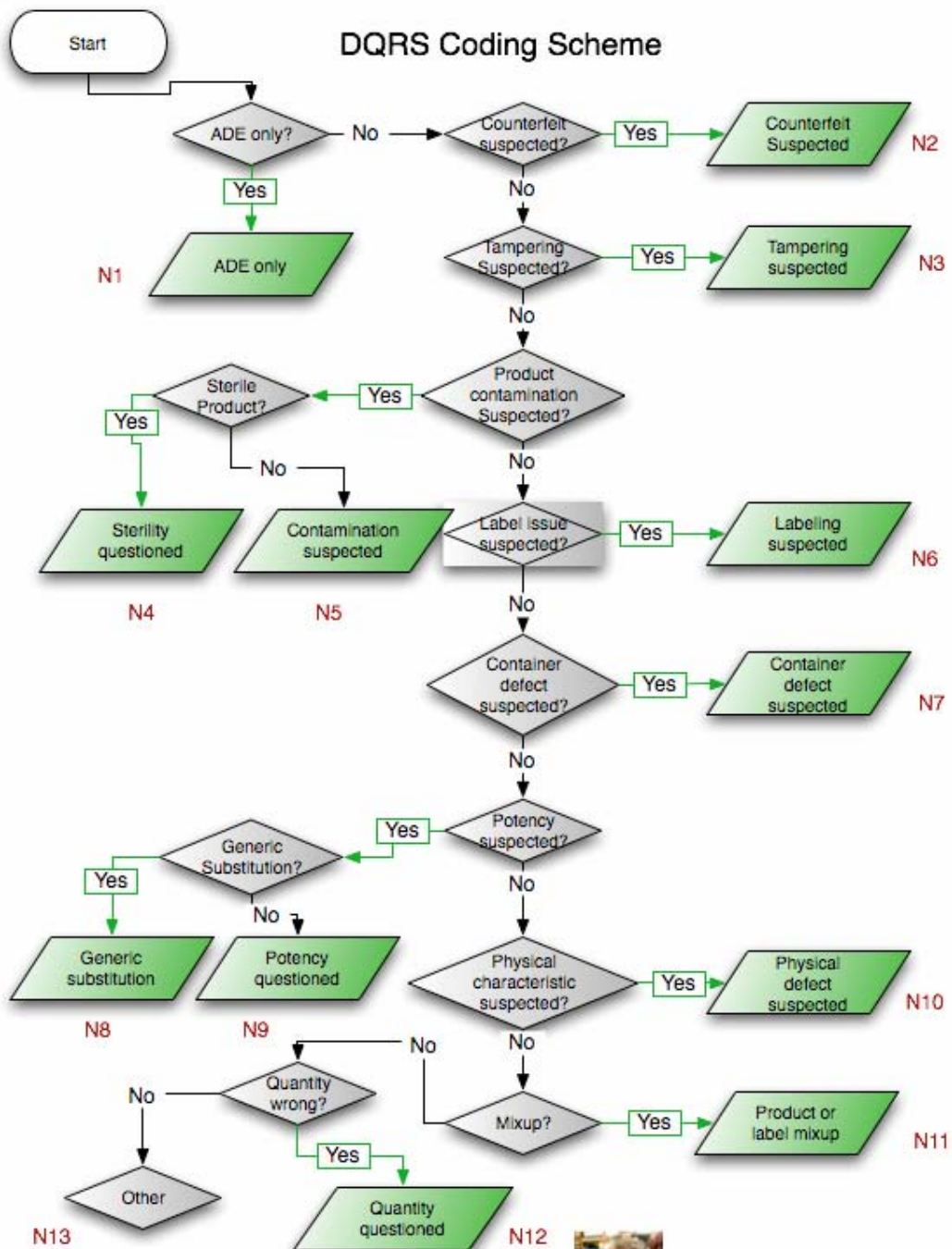
- Priority 1 - Imminent or serious health hazard
- Priority 2 - Potentially significant cGMP problems
- Priority 3 - Routine follow-up

# Source of DQRS Reports FY-05



# Total DQRS Reports Received





# Proposed Coding Scheme



N6

## LEVEL 1

0	6				
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## LEVEL 2

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MISSING

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WRONG

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QUALITY

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QUANTITY

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CONTENT

## LEVEL 3

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DISPENSING INFO

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LOT NUMBER

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BARCODE

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NDC NUMBER

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MISLEADING

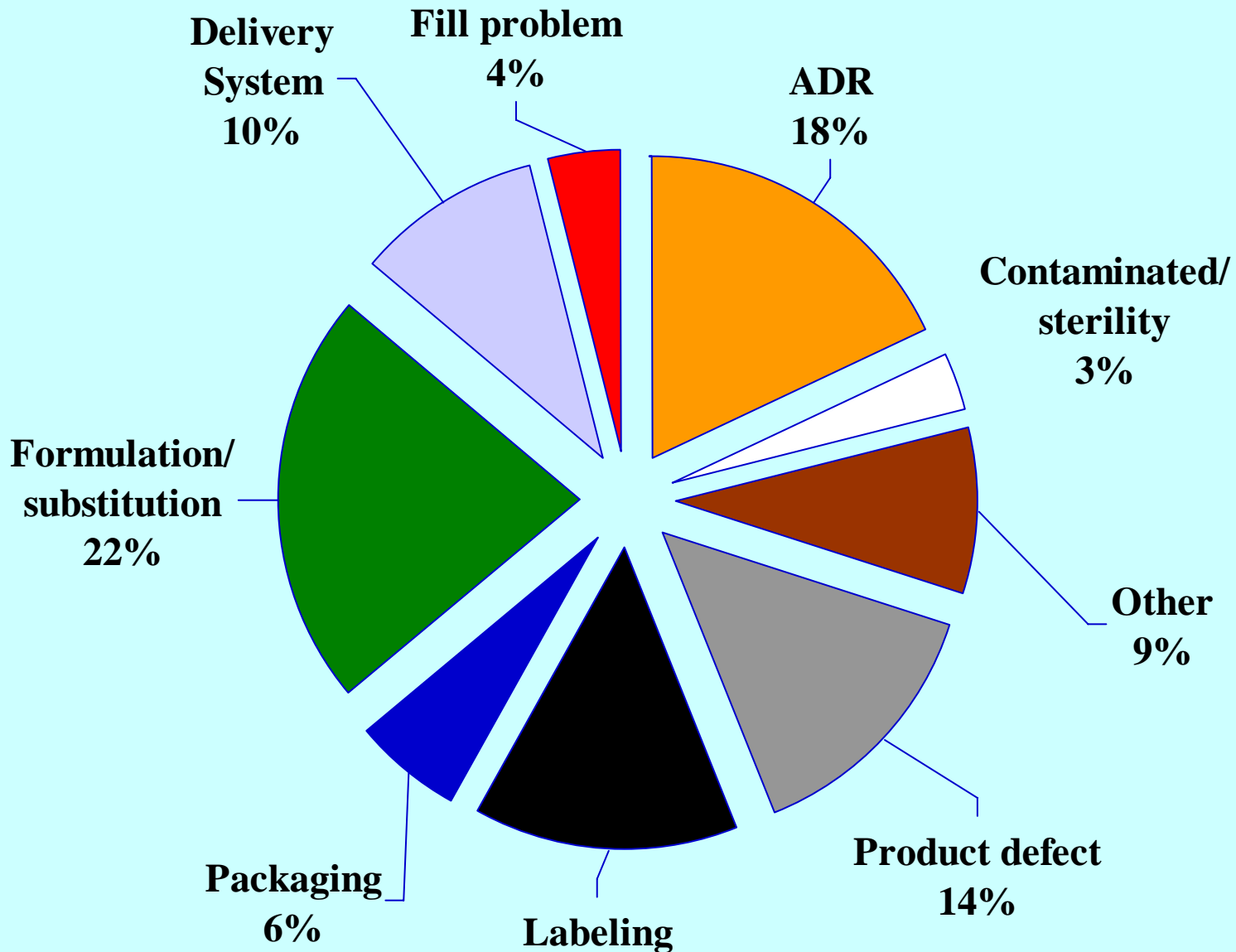
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INGREDIENT

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IMPRINTING

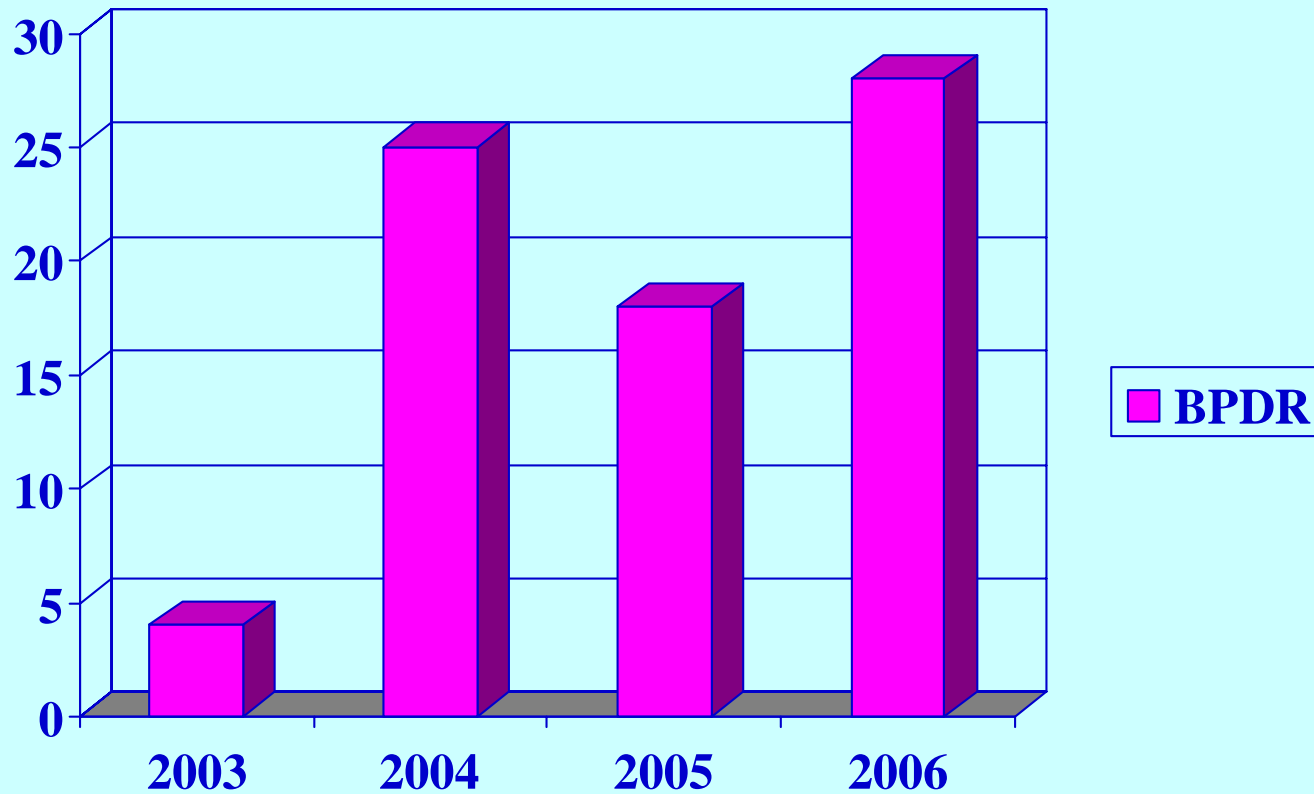
# DQRS Primary Defects Reported FY - 05



# Biological Product Defect Reports (BPDR)

- **October 1, 2003** –transfer of certain product oversight from the CBER to CDER.
- **June 30, 2003** – transfer of some therapeutic biological products from CBER to CDER.
- CBER and CDER regularly consult with each other whenever necessary.

# BPDR History



# BPDR Regulations

- Current Good Manufacturing Practice in Manufacturing, Processing, Packaging or Holding of Drugs; General (21 CFR 210)
- Current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR 211)
- Biological Products: General (21 CFR 600)  
General Biological Products Standards (21 CFR 610)

# BPDR Regulations (cont'd)

- **§ 600.14 Reporting of biological product deviations by licensed manufacturers.**
- (a) *Who must report under this section?* (1) You, the manufacturer who holds the biological product license and who had control over the product when the deviation occurred, must report under this section. If you arrange for another person to perform a manufacturing, holding, or distribution step, while the product is in your control, that step is performed under your control. You must establish, maintain, and follow a procedure for receiving information from that person on all deviations, complaints, and adverse events concerning the affected product.

# BPDR Triage Referrals

- BIOLOGICAL PRODUCT DEVIATION REPORT REFERRAL
- INITIAL\_\_\_\_\_ FOLLOW-UP\_\_\_\_\_FINAL\_\_\_\_\_
- DATE: 2006
- FROM: CAPT Juliaette Johnson, RN (klh)
- Drug Quality Reporting System Program Manager
- NDA Field Alert Program Manager
- Surveillance and Data Analysis Branch, HFD-332
- TO: Dr. Steven Kozlowski (NIH Campus) (Electronic Copy)
- Acting Director, OPS
- Office of Biotechnology Products
- (HFD-123 White Oak and NIH Campus) (Electronic copy)
- CC: LCDR Tia Harper-Velasquez (Electronic copy)
- Nick Buhay (Electronic copy)
- Brenda Uratani (Electronic copy)
- Sheila Rawls (Electronic copy)
- \_\_\_\_\_PMST Coordinator \_\_\_\_\_District Office (Electronic copy)
- 
- SUBJECT: BPD \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_
- BL Number (DQRS Tracking): B06-\_\_\_\_\_
- FIRM Product:
- 
- Please contact me at 301-827-8928 if you have any question(s) regarding this referral.

## BPDR (cont'd)

- To see which product classes have been transferred and which will remain at CBER, please refer to:

<http://www.fda.gov/cder/biologics/default.htm>

# MedWatch Reporting

- Telephone: 800 - FDA(332)-1088
- Postage Paid Form (3500)/Mailer
- FAX: 800-FDA(332)-0178
- Internet: <http://www.fda.gov/medwatch/>
- Report can be submitted on-line

All forms are online at:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>

# Program Contact

CAPT Juliaette Johnson, R.N., M.S.

VOICE - 301-827-8928

FAX - 301 827-8903

E-Mail: [juliaette.johnson@fda.hhs.gov](mailto:juliaette.johnson@fda.hhs.gov)